

Application No.: 10/695,295  
Amdt dated: October 8, 2008  
Reply to Office action of April 15, 2008

**Amendments to the Drawings**

Please replace drawing sheets number 1-5 with the attached replacement drawing sheets and add new drawing sheet 7. On sheet 1 of the Drawings, FIG. 1 is amended to add new callouts for items (14), (21), (30) and (32), and the leader to the callout for item (23) is amended to a hidden form. On sheet 2 of the Drawings, FIG. 3 is amended to add a new callout for item (52). On sheet 3 of the Drawings, FIG. 6 is amended to add a leader line to the callout for item (81a), a new callout is added for item (70a), and the leader for the callout for item (116) is moved to more clearly identify the node of the plug (81a). On sheet 4 of the Drawings, FIG. 8 is amended to add a new callout for item (50b). On sheet 5 of the Drawings, FIG. 9 is amended to add a new callout for item (50b) and two new callouts for item (132), and FIG. 14 is amended to add a new callout for item (145). New Drawing sheet 7 is added, including new FIGS. 16 and 17, to bring the Drawings into conformance with the Specification, as recommended by the Examiner in a telephonic Examiner interview on September 30, 2008. The amendments are supported by the Specification and Claims as originally filed and do not alter the scope of the claims.

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### Remarks/Arguments

This Amendment is filed in response to the Office action that was mailed on April 15, 2008. By this Amendment, Claims 1, 5 and 10 are amended. Claims 1, 2 and 4-10 are pending in this Application. The amendments do not introduce new matter as they are fully supported by the Claims, Specification and Drawings as originally filed or are inherent characteristics thereof. Applicants respectfully request reconsideration and allowance of all Claims in view of the following remarks.

Claim 5 is amended to change the term "first housing portion" throughout the claim to "distal housing portion" to provide proper antecedent basis for the claim. Applicants respectfully submit that the scope of the claim is not altered by this amendment. The Specification is also amended throughout by a replacement specification to correct inadvertent grammatical errors, replace items inadvertently removed in prior amendments, and to bring the Specification into conformance with the Drawings. Applicants respectfully submit that the amendments to the Specification are fully supported by the Specification, Claims and Drawings as originally filed, or are inherent characteristics thereof, and do not alter the scope of the claims.

### **Drawings**

Beginning on page 2 of the Office action, the Drawings are objected to as failing to comply with 37 C.F.R. § 1.84(p)(5) for not including the following reference signs mentioned in the description: **seal material 70** (page 11, line 8), **cylindrical walls 90**,

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**92** (page 11, line 21); **proximal housing portion 75b** (page 14, line 21) and **treads 130** (page 16, line 9). Applicants respectfully traverse this objection.

By this amendment, a callout for item (70) is included in new FIG. 16, and callouts for items (90) and (92) are included in new FIGS. 16 and 17. The Specification, at page 14, line 21, is amended to change the reference callout "75b" to "74b." The Specification, at page 16, line 9, is also amended to recite that the **threads 130** are depicted in FIG. 8.

It is also indicated in the Office action that the Drawings are objected to because FIG. 6 does not clearly show which element denotes the plug (81a) and the node (116). Applicants respectfully traverse this objection.

By this Amendment, FIG. 6 is amended to move the leader for the callout for item (116) to more clearly identify the node (116) of the plug (81a). Additionally, the Examiner indicated in a telephonic exchange on September 25-26, 2008, between Applicants' attorney and the Examiner, that the node is adequately depicted in the drawings.

Based on the foregoing, Applicants respectfully submit that these objections are overcome and respectfully request that these objections be reconsidered and removed.

### **Claim Rejections – 35 U.S.C. § 102**

Beginning on page 3 of the Office action, Claims 1, 2 and 4-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,460,616 to

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Weinstein et al. (Weinstein '616), and Claims 1 and 4-9 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,360,417 to Gravener et al. (Gravener '417). Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art. *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001). The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). In some circumstances, it is permissible to use multiple references in a 35 U.S.C. 102 rejection. See MPEP § 2131.01.

Amended Claim 1 recites: "A surgical valve having an axis extending between a proximal end and a distal end, comprising: a housing including a proximal housing portion and a distal housing portion **adjustably** cooperating with the proximal housing portion to define a gel cavity; a seal material disposed in the gel cavity, the seal material including a gel having non-compressible characteristics, the gel having characteristics

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for creating a pressure on an instrument extending through the valve to form a seal around the instrument; a proximal guide tube extending axially proximally from the proximal housing portion; the proximal guide tube facilitating insertion of a surgical instrument into the seal material; a distal guide tube extending axially distally from the distal housing portion, the distal guide tube facilitating retrograde insertion of the surgical instrument into the surgical seal, wherein the proximal guide tube includes exterior portions extending proximally of the proximal housing portion and interior portions extending distally of the proximal housing portion; and **means for adjustably moving the proximal housing portion axially relative to the distal housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve.**

Applicants respectfully submit that Weinstein '616 fails to disclose any means for **adjustably** moving the proximal housing portion axially relative to the distal housing portion to increase the pressure of the incompressible gel on the instrument and to create a **locking force** tending to inhibit movement of the instrument relative to the valve. Figures 2 and 3 of Weinstein '616 depict the proximal housing portion fixedly connected to the distal housing portion with a feature protruding radially inwardly on the proximal portion snapped into a groove on the distal portion. Weinstein '616 also discloses that the housing (14) is closed with a cap (16) (proximal housing) that may be snap fit in to place, having a snap-fit flange (18), or that cap (16) may otherwise be

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permanently sealed in position (Weinstein '616, column 2, lines 57-59). Having a snap-fit flange or, alternatively, being permanently sealed in position, the cap/proximal housing (16) of Weinstein '616 is not adjustable. Weinstein '616 further discloses that the catheter introducer is provided in which a catheter may be advanced therethrough with low friction (Weinstein '616, column 3, lines 45-48). With the catheter introducer being configured such that the catheter is advanced therethrough with low friction, the device of Weinstein '616 does not anticipate the gel creating a locking force against the instrument.

Based on the foregoing, Applicants respectfully submit that amended Claim 1 is patentable over Weinstein '616 and respectfully request that this rejection be reconsidered and removed. As Claims 2, 4 and 5 depend from Claim 1, Applicants respectfully submit that they are also patentable over Weinstein '616 as depending from an allowable claim and respectfully request that the rejection for these claims be reconsidered and removed as well.

Claim 6, as originally filed, recites: A surgical valve, comprising: a first housing portion defining a gel cavity; a seal material including a gel and having a node and an axial channel; a subassembly including the seal material disposed in the gel cavity, **the seal material being configured with the channel in an open state**; and a second housing portion disposed in juxtaposition to the first housing portion and applying a force to the seal material in the subassembly, **the force being of a magnitude sufficient to place the channel of the seal material in a closed state**.

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Applicants respectfully submit that Weinstein `616 fails to disclose a surgical valve having a seal material including a gel that is configured with an axial channel in an open state and a second housing portion that applies a force to the seal material sufficient to place the channel of the seal material in a closed state. Instead, as depicted in Figure 1 of Weinstein `616, the seal therein is formed in a closed state and does not change to an open state until an instrument is inserted therethrough, as depicted in Figure 3. Nowhere in Weinstein `616 does it indicate that the seal may be in an open state when no instrument is inserted therethrough.

Based on the foregoing, Applicants respectfully submit that Claim 6 is patentable over Weinstein `616 and respectfully request that this rejection be reconsidered and removed. As Claims 7-9 depend from Claim 6, Applicants respectfully submit that they are also patentable over Weinstein `616 as depending from an allowable claim and respectfully request that the rejection for these claims be reconsidered and removed as well.

Amended Claim 10 recites: A surgical valve adapted to form a seal around a surgical instrument extending through the valve, comprising: a first housing portion; a second housing portion **adjustably** engaging the first housing portion and defining with the first housing portion a gel cavity having a volume; a gel disposed within the gel cavity and having properties including flowability and incompressibility, the gel having characteristics for creating a pressure on the instrument to form a seal with the instrument; and means for **adjustably** moving the second housing portion axially

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relative to the first housing portion to increase the pressure of the incompressible gel on the instrument and to **create a locking force** tending to inhibit movement of the instrument relative to the valve

As with the arguments in relation to Claim 1, Applicants respectfully submit that Weinstein '616 fails to disclose any means for **adjustably** moving the proximal housing portion axially relative to the distal housing portion to increase the pressure of the incompressible gel on the instrument and to create a **locking force** tending to inhibit movement of the instrument relative to the valve. Figures 2 and 3 of Weinstein '616 depict the proximal housing portion fixedly connected to the distal housing portion with a feature protruding radially inwardly on the proximal portion snapped into a groove on the distal portion. Weinstein '616 also discloses that the housing (14) is closed with a cap (16) (proximal housing) that may be snap fit in to place, having a snap-fit flange (18), or that cap (16) may otherwise be permanently sealed in position (Weinstein '616, column 2, lines 57-59). Having a snap-fit flange or, alternatively, being permanently sealed in position, the cap/proximal housing (16) of Weinstein '616 is not adjustable. Weinstein '616 further discloses that the catheter introducer is provided in which a catheter may be advanced therethrough with low friction (Weinstein '616, column 3, lines 45-48). With the catheter introducer being configured such that the catheter is advanced therethrough with low friction, the device of Weinstein '616 does not anticipate the gel creating a locking force against the instrument.

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Based on the foregoing, Applicants respectfully submit that Claim 10 is patentable over Weinstein '616 and respectfully request that this rejection be reconsidered and removed.

Similar to the arguments above in relation to Claim 1 in view of Weinstein '616, Applicants respectfully submit that Gravener '417 fails to disclose any means for **adjustably** moving the proximal housing portion axially relative to the distal housing portion to increase the pressure of the incompressible gel on the instrument and to create a **locking force** tending to inhibit movement of the instrument relative to the valve. Applicants further submit that what is depicted and referred to in the Office action as a proximal housing portion (26, 28) and a distal housing portion (18, 20) are shown in an unassembled state wherein there is no gel. Figures 4 and 5 of Gravener '417 depict the "distal housing portion" being folded over the "proximal housing portion," wherein they overlap each other and form a gel pocket. However, when they are folded over each other, there ceases to be separate distal and proximal housing portions. There is no teaching in Gravener '417 for adjustably moving the "proximal" and "distal" housing portions in relation to each other after the gel is inserted into the gel pocket. Moreover, there is no means taught for increasing the pressure of the incompressible gel on the instrument to create a locking force tending to inhibit movement of the instrument relative to the valve.

Based on the foregoing, Applicants respectfully submit that Claim 1 is patentable over Gravener '417 and respectfully request that this rejection be reconsidered and

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removed. As Claims 4 and 5 depend from Claim 1, Applicants respectfully submit that they are also patentable over Gravener `417 as depending from an allowable claim and respectfully request that the rejection for these claims be reconsidered and removed as well.

Similar to the arguments above in relation to Claim 6 in view of Weinstein `616, Applicants respectfully submit that Gravener `417 fails to disclose a surgical valve having a seal material including a gel that is configured with an axial channel in an open state and a second housing portion that applies a force to the seal material sufficient to place the channel of the seal material in a closed state. Instead, as depicted in Figures 6-8 of Gravener `417, the seal therein is formed in a closed state and does not change to an open state until an instrument is inserted therethrough, as depicted in Figure 8. Nowhere in Gravener `417 does it indicate that the seal may be in an open state when no instrument is inserted therethrough.

Based on the foregoing, Applicants respectfully submit that Claim 6 is patentable over Gravener `417 and respectfully request that this rejection be reconsidered and removed. As Claims 7-9 depend from Claim 6, Applicants respectfully submit that they are also patentable over Gravener `417 as depending from an allowable claim and respectfully request that the rejection for these claims be reconsidered and removed as well.

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### **Claim Rejections – 35 U.S.C. § 103**

Beginning on page 7 of the Office action, Claim 2 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Gravener `417 in view of U.S. Patent No. 5,514,109 to Mollenauer et al. (Mollenauer `109). Applicants respectfully traverse this rejection.

As indicated above, Claim 1 is amended to include means for adjustably moving the proximal housing portion axially relative to the distal housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve. Applicants respectfully submit that Gravener `417 does not teach any means for **adjustably** moving the proximal housing portion axially relative to the distal housing portion to increase the pressure of the incompressible gel on the instrument and to create a **locking force** tending to inhibit movement of the instrument relative to the valve and that, therefore, Claim 1 is allowable over Gravener `417. Applicants also respectfully submit that Mollenauer `109 does nothing to correct these deficiencies. As Claim 2 depends from Claim 1, it is allowable over Gravener `417 in view of Mollenauer `109 as depending from an allowable claim. Accordingly, a prima facie case of obviousness has not been established and hence reconsideration and withdrawal of the rejection of Claim 2 is respectfully requested.

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### **Summary of Examiner Interview**

On September 5, 2008, Applicants' attorney, David Majdali, and Examiner Quynh-Nhu Hoang Vu engaged in a telephonic Examiner Interview. Claims 6 and 10 of the present Application were discussed in view to the rejections under 35 U.S.C. § 102 in relation to Weinstein '616 and Gravener '417, respectively. Regarding Claim 6, the Examiner agreed that Gravener '417 fails to disclose a channel in the seal that is open in its natural state. Regarding Claim 10, the Examiner agreed that the claim would be patentable over the cited references if amended as discussed. In a follow-up telephonic exchange between David Majdali and Examiner Vu on September 25 and 26, 2008, the Examiner agreed that the drawings show the node (116) sufficiently clear. In a further telephonic Examiner interview between David Majdali and Examiner Vu on September 30, 2008, the Drawings were discussed in view of the Specification. The Examiner recommended adding new figures to bring the Drawings in conformance with the Specification. In view of the Examiner's recommendation, new FIGS. 16 and 17 were added. The amendments are supported by the Specification and Claims as originally filed and do not alter the scope of the claims.

### **Conclusion**

In view of the foregoing remarks, it is respectfully submitted that this application is in condition for allowance. Accordingly, reconsideration of the application and allowance of Claims 1, 2 and 4-10 are respectfully requested. Applicant also respectfully submits that the noted features are merely exemplary and/or illustrative and

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does not disavow any claim scope or define any elements or terms in the claims in such a way other than as recited or provided in the claims and their equivalents. Likewise, any characterization of the features in relation to the claims are merely exemplary and/or illustrative and thus Applicant does not disavow any claim scope or specially define any elements or terms in the claims in such a way other than as recited or provided in the claims and their equivalents. Consequently, Applicant has not advanced every argument for the allowability of the claims over the references of record. As such, Applicant does not acquiesce to any of the Examiner's statements or characterizations not specifically traversed. If the Examiner should have any remaining questions or objections, a telephone interview to discuss and resolve these issues is respectfully requested.

Please charge any additional fees, including any fees for additional extension of time, or credit any overpayment to Deposit Account No. 01-2215.

Sincerely,

APPLIED MEDICAL RESOURCES

BY

  
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